Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0295576	02/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Intercoastal Medical Group Inc	943 S Beneva Rd Ste 102, Sarasota, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Intercoastal Medical Group Inc on 02/19/25 to 02/20/25. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076 - 493.1441 Laboratory Director High Complexity
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to evaluate the competency of the Technical Consultant and one Testing Personnel (TP-A) of six Testing Personnel (TP-A, B, C, D, E, and F) to assure their competency to perform test procedures and report test results promptly, accurately and proficiently for two of two years (2023-2024). Findings included: 1. Review of the CMS-209 Laboratory Personnel Report, signed by the Lab Director on 2/3/25, listed one Technical Consultant (who was also listed as TP-A) for the clinical laboratory testing. 2. No documentation of competencies for the Technical Consultant/TP-A for 2023-2024 were presented for review. 3. The Laboratory Director (who is also the Technical Supervisor for High Complexity testing) confirmed on 2/20/25 at 11:30 AM there was no competency documentation for the Technical Consultant/TP-A for 2023-2024.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform Histopathology testing within the laboratory's stated performance specifications for one (2024) of two years (2023-2024). Findings included: 1. The Histopathology Manual was approved by the Lab Director 7/27/2022 and included a policy for the Thermo Fisher embedding instrument effective 10/1/2018. The policy showed the acceptable paraffin temperature range was 57-65 degrees Celsius. 2. The Embedding Center Temperature and Maintenance Log showed temperature range was 56-65 degrees Celsius (not the same as the policy). The 2024 log documented the temperature as 70 degrees Celsius for each day of testing, which was not within the acceptable temperature range of the policy and/or the Embedding Center Temperature and Maintenance Log. 3. On 2/20/25 at 1:20 PM the Histology Tech and the Technical Consultant both confirmed the temperature was outside of the acceptable temperature for 2024.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a record system that included the identity of the personnel who performed the grossing component of Histopathology testing for two of two years (2023-2024). Findings included: 1. Patient #1 and Patient #2 final reports failed to include documentation of who performed the grossing of the tissue samples. A request for documentation to show how the laboratory recorded who of the two grossing Testing Personnel (TP-E and TP-F) performed grossing on the patient samples. 2. The Histopathology Tech and Technical Consultant both confirmed on 2/20/25 at 1:20 PM there was no record system in place for 2023-2024 to identify the personnel who performed the grossing component of Histopathology testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on interview and record review, the Laboratory Director failed to provide overall management failing to fulfill their responsibilities for two of two years (2023

	and 2024). The Laboratory Director failed to establish a quality assessment program to identify failures (see D6093).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Lab Director failed to ensure a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred for two years, 2023 and 2024. Findings included: 1. Laboratory Policy "Quality Control Program", approved by the Lab Director 10/15/2014 outlined components to be reviewed annually. These components included preanalytic, analytic, proficiency testing, continuing employee education, and safety. 2. Interview with the Lab Director on 02/20/2025 at 11:16 am confirmed the laboratory does not document quality assessment activities. 3. The Lab Director failed to identify through a QA program the laboratory had failed to perform Histopathology testing within the laboratory's stated performance specifications for one (2024) of two years (2023-2024). (See D5411). 4. The Lab Director failed to identify through a QA program the laboratory failed to maintain a record system to identify the personnel who performed the grossing component of Histopathology testing for two of two years (2023-2024). (See D5787) 5. The Lab Director failed to identify through a QA program that one Testing Personnel (TP-F) of two Testing Personnel performing Histopathology grossing had received training, and the competencies of the Technical Consultant and three (TP-A, TP-E, and TP-F) of six Testing Personnel was performed to assure their competency to perform test procedures and report test results promptly, accurately and proficiently for two of two years (2023-2024). (See D5209 and D6120)
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor failed to assure that one Testing Personnel (TP-F) of two Testing Personnel (TP-E and TP-F) performing Histopathology grossing received training since the date of hire (4/29/2024) and failed to evaluate competency for two (TP-E and TP-F) of six Testing Personnel (TP-A, TP-B, TP-C, TP-D, TP-E, and TP-F) for two of two years (2023-2024). Findings included: 1. Review of the CMS-209 Laboratory Personnel Report, signed by the Lab Director on 2/3/25, listed TP-E and TP-F as only performing Histopathology testing (grossing). TP-F was hired 4/29/2024 for the Histopathology lab. 2. No documentation of training and competency was presented for TP-F for the

	Histopathology testing performed since the 4/29/2024 hire date. 3. No documentation of competencies for TP-E for the Histopathology testing performed for 2023-2024 was present for review. 3. The Laboratory Director (who is also the Technical Supervisor for Histopathology) confirmed on 2/20/25 at 11:15 AM there was no documentation of training and competency of TP-F prior to performing patient testing (grossing) independently and no competencies for TP-E for 2023-2024.